

Remarks

Entry of the present amendment and reconsideration of this application is respectfully requested. Upon entry of the foregoing amendment, claims 1, 2, 5-10, 13-15 and 24-27 are active in the application. Claims 16-18 and 21-23 are pending but withdrawn. Claims 3, 4, 11, 12, 19 and 20 are canceled without prejudice or disclaimer.

The amendment to the specification corrects a typographical error. Support for this amendment is found, *inter alia*, at English language specification page 24, line 15.

Support for amending the independent claims is found, *inter alia*, at English language specification page 11 (lines 10-19) and original claim 7.

Support for the amendment to claims 10 and 18 is found, *inter alia*, at English language specification page 4 (lines 18-22).

New claims 24-27 add back certain dependent embodiments that had been canceled by preliminary amendment to avoid nested multiply dependent claims. Support for new claim 24 is found, *inter alia*, at English language specification page 3 (lines 23-24). Support for new claim 25 is found, *inter alia*, at English language specification page 5 (lines 1-2). Support for new claims 26 and 27 is found, *inter alia*, at English language specification page 5 (lines 3-4).

These changes are believed to introduce no new matter, and their entry is respectfully requested.

Based on the above amendment and the following remarks, Applicants respectfully request that the Examiner reconsider all outstanding objections and rejections and that they be withdrawn.

The Restriction Requirement

Applicant sincerely thank the Examiner for the telephonic discussion of August 15, 2008, to clarify the restriction requirement of January 9, 2008.

The original restriction requirement refers to Group I as being claims 1-15 and to Group II as being claims 9-12. However, in the telephone discussion, the Examiner clarified for the record that Group I did include all of claims 1-15 and for Group II, it was intended that claims 16-23 be listed, directed, as stated in the restriction requirement, to the process for producing the composition. Applicants elected Group I, claims 1-15 in reply to the restriction requirement. This understanding is consistent with the Office action, which shows that claims 16-23 are withdrawn as being directed to a non-elected invention.

Accordingly, Applicants understand that they are entitled to file a divisional application to non-elected Group II, claims 16-23, and to enjoy the full protection of 35 U.S.C. § 121 for such divisional application. Applicants respectfully request that the Examiner kindly indicate the same for the record in reply to this communication.

Rejection under 35 U.S.C. § 102(b)

At Office action page 3, claims 1-15 are rejected under 35 U.S.C. § 102(b) are being anticipated by Bouloumie *et al.*, US 6,284,277 B1 (herein "Bouloumie"). Applicants respectfully traverse this rejection.

Inter alia, Examiner states that Bouloumie teaches a freeze-dried formulation consisting of an amorphous phase and a crystalline phase, which is pharmaceutically acceptable, comprising at least one nonprotein active ingredient, characterized in that it contains mannitol and alanine. Examiner states that the freeze-dried product of Bouloumie consists of an amorphous phase and a crystalline phase and that the amorphous phase predominantly consists of mannitol and an active ingredient. Examiner states that vitamins used in the formulation include cobalamin and that the cobalamin family comprises vitamin B12. Applicants respectfully request reconsideration.

Even if Bouloumie discloses a freeze-dried formulation consisting of an amorphous phase and a crystalline phase, which is pharmaceutically acceptable, comprising at least one nonprotein active ingredient, characterized in that it contains mannitol and alanine (See Bouloumie's abstract), Bouloumie does not teach or fairly suggest the currently claimed invention in which the independent claims recite that the sugar or sugar alcohol that is in the amorphous state in the excipient is present in an amount of at least 20% of the total weight of the excipient.

Accordingly, Bouloumie does not anticipate the claimed invention and this rejection can be withdrawn.

Conclusion

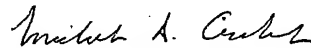
All of the stated grounds of objection and rejection have been properly traversed, accommodated, or rendered moot. Applicants therefore respectfully request that the Examiner reconsider all presently outstanding objections and rejections and that they be withdrawn.

Applicants believe that a full and complete reply has been made to the outstanding Office action and, as such, the present application is in condition for allowance. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of this Amendment and Reply is respectfully requested.

Respectfully submitted,

STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.



Michele A. Cimbala
Attorney for Applicants
Registration No. 33,851

Date: August 27, 2008

1100 New York Avenue, N.W.
Washington, D.C. 20005-3934
(202) 371-2600

851287.1